

PROSLIDE 32 B System

Mobile radiographic unit with DR-System

Model/ID: 7017-9-0000
Basis UDI-DI: 426050264X020ZF

System instructions for use shortform

Ident. Nr. 5017-0-0002



(Example configuration without RAPIXX-DR System)

Responsible for putting devices together
to this system acc. to Article 22 of
Regulation (EU) 2017/745:

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NOTE

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NOTE

The information contained in this System Quick Reference Guide is consistent with the system configuration as of the date of shipment. Changes made after delivery are incorporated in a new version of this document.

Current versions of the document can be called up at any time on the PROTEC website.

Document effectivity

Revision	Date	List of effective pages	Comment	Author
1.0	2017-03-13	all	Original issue	ML
2.0	2019-11-29	3, 4, 8	NOTE changed; Cap. 1 new; Cap. 3.1 WARNING new	ML
3.0	2020-11-03	Title page, 5	Model/ID, Intended use	ML
4.0	2021-07-20	Title page, 5, 6	change to article 22	ML

Radiation warning



WARNING!

The system described in this document is intended for the generation of X-rays in medical diagnostics.

X-rays generate a potential risk for both patients and operators.

For this reason the application of X-rays for a given medical purpose must aim at the minimization of radiation exposition to any person.

Those persons responsible for the application must have the specific knowledge according to legal requirements and regulations and must establish safe exposure procedure for these kind of systems. The responsible persons for planning and installation of this equipment must observe the national regulations.

1 Product description

1.1 Introduction

This System Quick Guide summarizes the most important information for efficient and effective operation of the PROSLIDE 32 B system.



NOTE

Before you work with the PROSLIDE 32 B System, it is imperative that you read the applicable instructions for the two system components PROSLIDE 32 B and RAPIXX DR System with detailed safety and handling instructions. These documents are in charge and valid in their current version.

1.2 Intended use

The PROSLIDE 32 B Systems as mobile general-purpose diagnostic X-ray systems with DR-System are intended in a variety of routine planar x-ray imaging applications in human medicine. They are used in hospitals and enable the acquisition, image processing and transmission of digital, conventional X-ray images at various locations within the hospital.

1.3 Clinical Benefit

The clinical benefit of using diagnostic X-ray systems in human medicine is the generation of conventional two-dimensional X-ray images for creation or specification of findings as a basis for treatment decisions.

1.4 Patient target group

The intended patient group includes all people for whom a justifying indication for a medical X-ray has been given by a physician with the necessary expertise in radiation protection.

There are no general or fundamental restrictions on the patient group regarding age, gender, origin and patient condition.

1.5 Medical conditions to be diagnosed

A complete list of indications is unrealisable for conventional radiography, because the spectrum of conventional X-rays is very diverse and can vary in the course of medical-technical progress.

Some examples of indications for an X-ray examination may be:

- For the diagnosis of a bone fracture or bony injuries of the skeletal system or pathological changes of hard tissues.
- To control the bone setting.
- For the diagnosis of luxations and ligament ruptures of the locomotor system.
- For the diagnosis of degenerative, inflammatory, traumatic and tumorous diseases and changes of the locomotor system.
- For diagnostic of malformations and malalignments of the skeletal system.
- For the diagnosis of thoracic and pulmonary symptoms (thorax exposures)
- For the diagnosis of sclerotherapy.
- For the diagnosis of inflammatory and expansive processes of the mucosa, cranial bones and paranasal extension.
- For the diagnosis of the abdomen (e.g. acute abdomen, plain abdominal radiography, urethrogram, cystogram).

1.6 Indications and Contra Indications

1.6.1 Indications

According to §83 of the German radiation protection law (StrlSchG), an X-ray examination is only justified if the patients benefit from x-ray diagnostics outweighs the radiation risk. The examination method, means the conventional X-ray with the PROSLIDE 32 B System, must be suitable to answer the diagnostic question and no other more suitable alternative method is available.

Accordingly, it is also described by the International Atomic Energy Agency (IAEA) in the document Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (Requirement 37: Justification of medical exposures). It also refers to the need to consider national or international guidelines for the justification of a medical exposure.

**NOTE**

Even if, according to the justifying indication, the benefit predominates the radiation risk, it must not be disregarded that there are residual risks due to ionising radiation and that undesirable side effects may occur. Ionising radiation (X-radiation) can damage the genome and, in the long term, lead to cancer and mutations and thus damage the human body.

1.6.2 Contra Indications

There are no absolute contraindications for conventional X-rays. But it is not allowed to make any exposures on humans when they are not medically indicated (see Justification of medical exposures). For pregnant women and children it is important to consider if the exposure is really necessary. It should be avoided if possible.

1.7 Intended user group

The mobile radiographic system PROSLIDE 32 B is exclusively designated for use by professional who are trained, in accordance with the corresponding national regulations, in the use of diagnostic X-Ry equipment and its proper intended use in connection with other medical devices, objects and accessories.

Suitable users could include the following: Radiologist, radiology assistants, radiology technicians, doctors and other medically trained personnel.

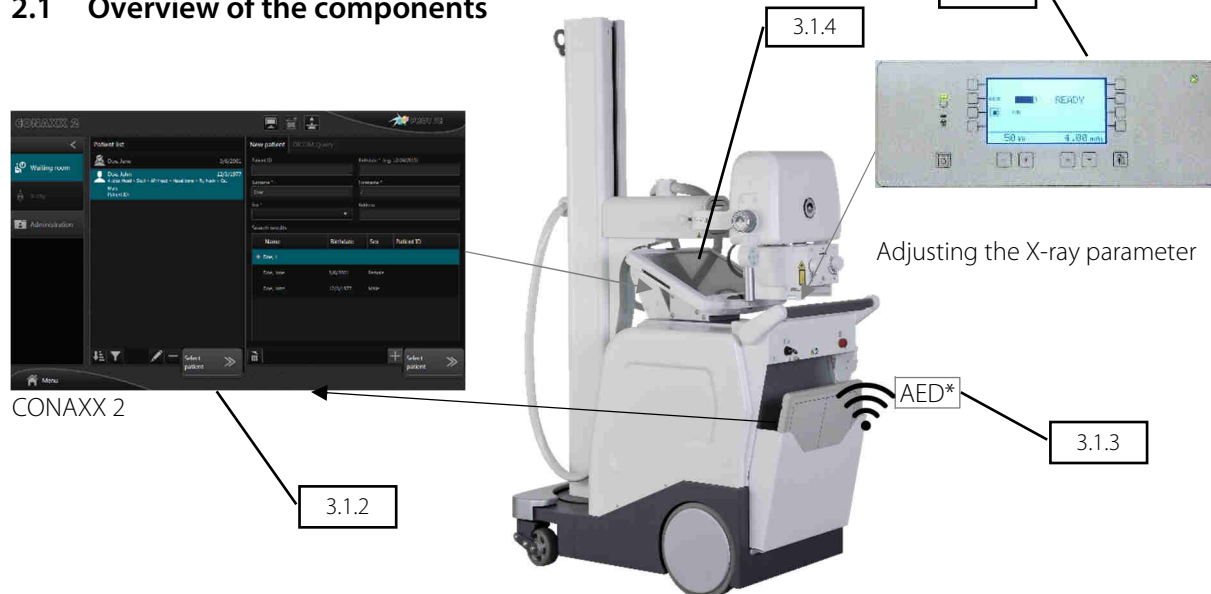
1.8 Declaration according to Article 22

The Declaration according to Article 22 of Regulation (EU) 2017/745 is available on request from PROTEC:

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2 Operating Elements and Displays

2.1 Overview of the components



* AED – Automatic Exposure Detection

2.1.1 Operating Elements and Displays PROSLIDE 32 B

You can find further information of the mobile X-ray unit in the user manual for this component.

2.1.2 Operating Elements and Displays of the CONAXX 2 Software

You can find further information of the CONAXX 2 in the user manual for this component.

2.1.3 Operating Elements and Displays of the RAPIXX System

You can find further information of the RAPIXX-systems in the user manual for this component.

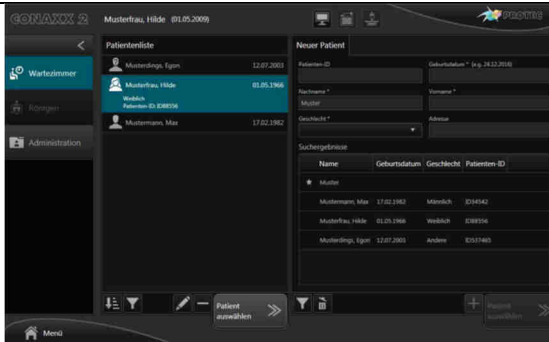
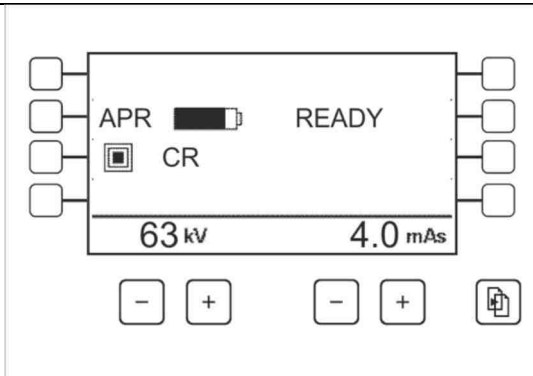
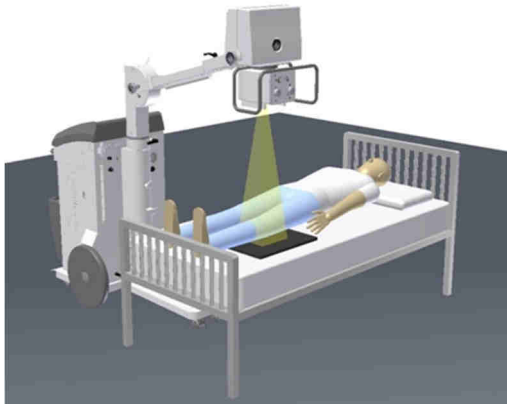

2.1.4 Operating Elements and Displays of the Panel-PC*

You can find further information of the Panel-PC in the user manual for this component.

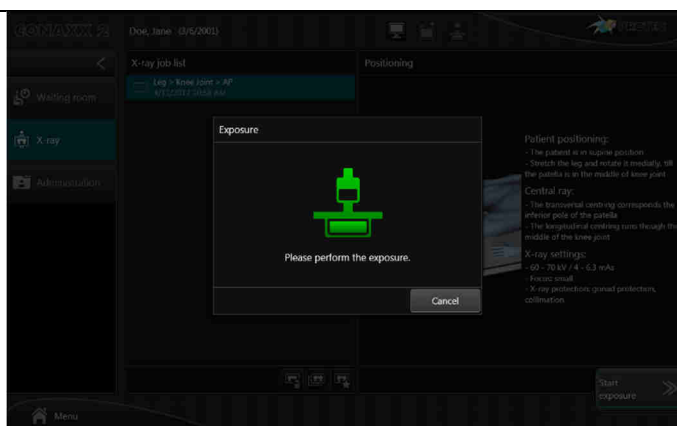
* Not included in delivery. Please order separately.

3 Handling

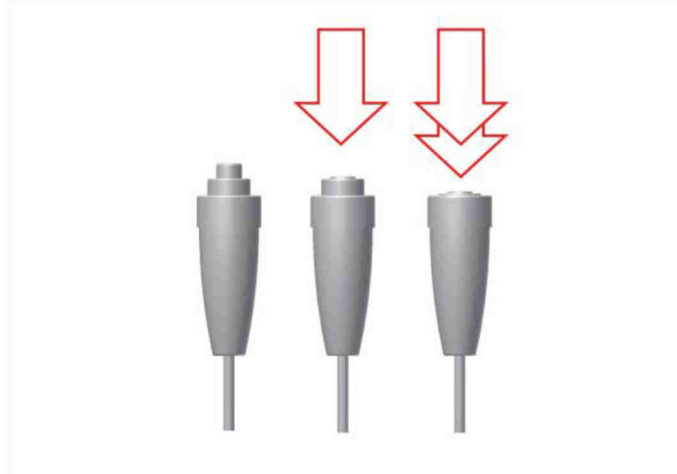
3.1 Operation

Description	Picture
Switch on the PROSLIDE 32 system	Switch-on sequence: <ul style="list-style-type: none"> - Generator - RAPIXX DR-System - Panel-PC*
Start CONAXX 2	
Chose patient and region of interest in CONAXX 2	
Prepare exposure in CONAXX 2	
Set up generator values	
Position detector, y-ray tube and patient	
<div style="display: flex; align-items: center;">  <div> <p>WARNING!</p> <p>The central beam and the detector surface (or CR or film) should always be positioned orthogonally to each other and centrally in the beam field for optimum imaging. The active surface of the detector (or CR or film) must always point towards the radiation field.</p> </div> </div>	

Prepare CONAXX for exposure



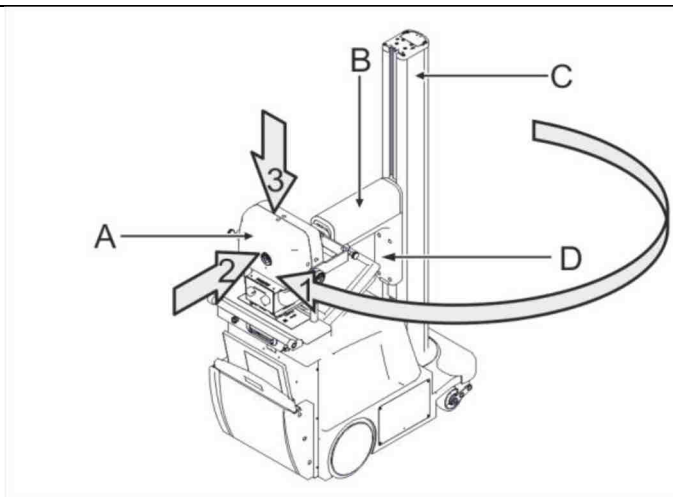
Make the exposure



View the image



Prepare X-ray tube and detector for next exposure or bring them into transport position



Copy exposures to the clinical system

Detailed information of using the components can be found in the respective user manual.

3.1.1 Operation of PROSLIDE 32 B

Detailed information of using the PROSLIDE 32 B can be found in the user manual.

3.1.2 Operation of CONAXX 2

Detailed information of using the CONAXX 2 can be found in the user manual.

3.1.3 Operation of the RAPIXX-DR System

Detailed information of using the RAPIXX-DR system can be found in the user manual.

3.1.4 Operation of Panel-PC*

Detailed information of using the PANELPC can be found in the user manual.

3.2 Functions of the PROSLIDE 32 B SYSTEM

3.2.1 Switching the PROSLIDE 32 B system OFF and ON

To switch on the complete PROSLIDE 32 B system it has to be switched on 3 components. We recommend the following sequence of switching on:

1. Generator (PROSLIDE 32 B)
2. RAPIXX DR-System
3. Panel-PC*

Detailed information about switching on the component can be found in the respective user manual.

* Not included in delivery. Please order separately.